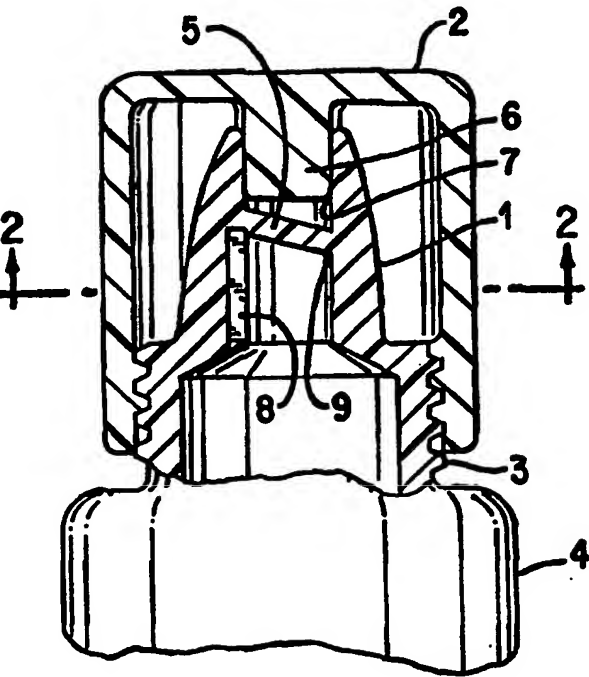


**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup>:</b> <b>B6SD 47/18</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 96/00173</b> <b>(43) International Publication Date:</b> 4 January 1996 (04.01.96)
<b>(21) International Application Number:</b> PCT/US95/07708 <b>(22) International Filing Date:</b> 22 June 1995 (22.06.95) <b>(30) Priority Data:</b> 265,351 24 June 1994 (24.06.94) US <b>(60) Parent Application or Grant</b> <b>(63) Related by Continuation</b> US 265,351 (CIP) Filed on 24 June 1994 (24.06.94) <b>(71) Applicant (for all designated States except US):</b> MERCK & CO., INC. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> LIFSHEY, Arthur, L. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US). <b>(74) Common Representative:</b> MERCK & CO., INC.; 126 East Lincoln Avenue, Rahway, NJ 07065 (US).		<b>(81) Designated States:</b> AM, AU, BB, BG, BR, BY, CA, CN, CZ, EE, FI, GE, HU, IS, JP, KG, KR, KZ, LK, LR, LT, LV, MD, MG, MN, MX, NO, NZ, PL, RO, RU, SG, SI, SK, TJ, TM, TT, UA, US, UZ, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> NON-STREAMING OPHTHALMIC TIP AND DELIVERY DEVICE  <b>(57) Abstract</b> <p>This invention consists of an ophthalmic dispensing tip (1) formed by injection molding, which has a one-piece molded tip (1) to be used with a mating cap (2), the tip (1) having an internally molded breakaway barrier membrane (5) inside the flow channel, and the cap (2) having a shaped stud (6) fitting inside the tip (1), so that the final clockwise half turn of the cap (2) pushes the stud (6) against the barrier (5) and displaces it, thereby creating a restricted path (8) through which the contents are dispensed.</p> 		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

- 1 -

TITLE OF THE INVENTION

## NON-STREAMING OPHTHALMIC TIP AND DELIVERY DEVICE

TECHNICAL FIELD

5           This invention relates to a liquid dispensing tip and cap especially useful in the dispensing of ophthalmic drugs which typically need to be dispensed in the form of a drop, and a novel method of manufacturing the device.

10   BACKGROUND OF THE INVENTION

          The present invention pertains to the art of liquid dispensers, and, more particularly, to a dispensing tip for accurately dispensing small droplets of liquid. The invention is particularly applicable for use as an eyedropper to dispense ophthalmic drugs and will be described with particular reference thereto although it will be appreciated that the invention has other and broader applications.

15           Medicant drop dispensers of the type to which the present invention pertains are available in various sizes and shapes for the numerous medicines and solutions which are available for the care and comfort of the human eye. Such dispensers are basically comprised of a relatively small compressible plastic container or vial provided with a dispensing tip and cap.

          One problem associated with conventional eyedroppers is the difficulty in accurately controlling the amount of medicine dispensed, i.e., the number of drops dispensed. Many conventional eyedroppers utilize one or a combination of methods to achieve single drop control.

25           One method uses a highly compliant plastic bottle which the user squeezes to dispense a drop. The extensive deflection of the bottle creates an significant internal air pressure within the vial which expels the liquid through the tip. In order to prevent a continuous stream of liquid medicant from being expelled, and to create single drops, these bottles sometimes incorporate a flow restriction at the inlet of the tip or nozzle. This flow restriction tends to limit the number of drops

30

- 2 -

expelled during a single squeeze. It limits the liquid medicant flow rate favoring the formation of individual drops releasing from the dropper tip rather than a continuous stream. Unfortunately, the creation of a very small molded orifice, frequently as small as .005" (.13 mm) in diameter creates manufacturing difficulties, since the plastic injection molds must have corresponding small fragile (.005" dia./ .13 mm dia.) core pins.

#### SUMMARY OF THE INVENTION

The present invention discloses an ophthalmic tip and cap system providing nonstreaming drop control, the tip having an internally molded dislodgeable barrier which may be hinged on one side, the cap having a stud shaped to fit inside the nozzle tip, so that the downward axial movement of the cap either partially or completely displaces the barrier. The tip may have molded flow restriction groove(s) or slot(s) on its internal flow channel. The cap of the device is designed such that upon downward motion of the cap, the tip barrier is partially displaced resulting in subsequent mechanical captivation of the barrier in its open position to create a flow restriction. The cap may also be designed so that the tip barrier is completely displaced by the downward movement of the cap and subsequent mechanical captivation of the barrier in its open position to create a flow restriction.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig 1 a cross-sectional view of the tip affixed to a bottle and the mating cap in the unactivated position where the barrier membrane 5 is angled relative to the activating stud (6).

Fig 1(a) is a cross-sectional view of the tip affixed to a bottle and the mating cap in the unactivated position where the barrier membrane 50 is circular in shape and lies parallel to the face of the activating stud (6) and perpendicular to the tip (1).

- 3 -

- Fig 1(b) is a cross-sectional view of the tip affixed to a bottle and the mating cap in the unactivated position where the barrier membrane 51 is spherical in shape and is removably attached to the tip (1).  
Fig 2 is a cross-sectional view through section 2-2 of Fig. 1.  
5 Fig 2(a) is a cross-sectional view through section 2-2 showing four slots(8) rather than a single slot (8).  
Fig 2(b) is a cross-sectional view through section 2-2 showing a plurality of slots (8).  
Fig. 3 is a cross sectional of view through the tip and a portion of the  
10 cap which shows the barrier after being activated.  
Fig. 3(a) and Fig 3(b) show the device of Fig 1(a) and Fig 1(b) in the activated position where the barrier 50 and 51 are totally dislodged from their original position.  
Fig. 4 is a cross sectional view of the tip in the inverted position with  
15 the flow path (10) indicated.  
Fig 4(a) and Fig 4(b) are cross sectional views of the tip in the inverted position with the flow path (10) indicated for the device as shown in Fig 1(a) and Fig 1(b) respectively.  
Fig. 5 is a side view and partial cross sectional view of the tip when  
20 integrally molded as part of an injection molded vial for the delivery of medicament.

#### DETAILED DESCRIPTION OF THE INVENTION

25 The present invention contemplates a new and improved tip and cap for ophthalmic use, which overcomes the above-referred to manufacturing difficulties and which accurately dispenses droplets of liquid medicant at desired locations as discrete drops. Single drops having a volume of approximately 30-50 microliters are typical in the art, but larger or smaller drops, can be provided by adjusting size and  
30 geometry of the tip.

In accordance with the present invention there is provided an improved tip (1), or drop dispenser for use with a closed compressible container. The preferred tip (1) is integrated into a simple one piece molded device, together with a mated cap (2) which is

- 4 -

best understood by reference to the accompanying drawings. The tip/cap combination also serves as a means for providing an hermetically sealed tip which can be activated (opened) only when ready for use. This can be accomplished by only partially assembling the cap  
5 (2) onto the tip (1), so that the cap (2) does not displace the membrane (5) or barrier (5), (50) or (51) in the tip (1). The tip thus remains hermetically sealed, eliminating the possibility of minor leaks of liquid or vapor during long storage periods.

Figure 1 is a vertical sectional view of the one-piece  
10 molded tip having a cap with screw threads engaged around the tip.

Figure 2 is a cross-section of Figure 1 taken along line 2-2, showing a restricted flow channel side slot. Figures 2a and 2b are alternate embodiments showing other restricted slot(s) or groove(s).

Figures 3 and 4 are vertical sectional views of the tip  
15 showing the action in opening the cap and the restricted flow path, which prevents streaming.

Figures 3A, 4A and 3B, 4B each show additional embodiments of this device.

Figure 5 is a diagrammatic view of an example of an  
20 ophthalmic container having the tip with cap of this invention in place.

The actual bottle design is not a critical part of this invention. Any of the ophthalmic containers presently available can be used with the tip of this invention. The bottle design illustrated, which is especially preferred, is one having a limited displacement area, such  
25 as described in the invention claimed in U.S.S.N. 08/200,676, filed Dec. 22, 1993, attorney Docket No. 19140.

Referring to the drawings, the key aspects of this invention are described as follows.

In Figure 1, the ophthalmic tip, shown generally at (1), is  
30 protected by a cap (2), attached through screw threads (3). The bottle, which can be any type bottle useful for dispensing ophthalmic medicaments, is indicated generally at (4).

The cap (2) serves as a "seal-break". The tip is formed with a dislodgeable membrane or barrier (5) across the opening. The

- 5 -

embodiment shown is eliptically shaped, and slanted so that it is attached higher inside the tip, at a point above a side slot (8). Other embodiments shown in Figure 1A and 1B can include a circular barrier (50) or spherical barrier (51) attached circumferentially to the inside wall of the tip (1). The inside of the cap (2) fitting over the nozzle opening is fitted with a suitably sized and shaped integrally molded stud (6). The cap (2) can be designed so that a final clockwise half-turn of the cap pushes the stud (6) against the barrier or membrane (5), (50) or (51) and downwardly displaces it while it remains attached at hinge point (9) to inside wall (7). Alternatively, the cap (2) and bottle (4) may be so designed so that the stud (6) is moved downward against barrier (5) by axial force applied to the cap. Other embodiment of this invention would have stud (6) completely dislodge barrier (50, 51) to a new position, which would break the hermetic seal and create a suitable flow restriction. In all cases, the barrier would be captivated in its new open position by friction fit, undercuts, or other mechanical means, allowing it to function as a flow restrictor able to resist the internal pressure generated in the vial during dispensing. Alternatively, the slot (8) in Fig. 2 may be of various sizes to allow for flow characteristics and viscosity of diverse fluids. Slot (8) may also consist of any number of shallow slots, as dictated by the flow properties.

The restricted flow channel side slot (8) is an important part of this invention, as it serves to aid in the prevention of a stream of medicament. Its shape in cross section is shown in Figures 2, and alternative embodiments shown in Fig. 2A and Fig. 2B wherein it can clearly be seen as molded slot(s) (8) or groove(s) in the nozzle channel.

Once the cap (2) is pushed or screwed down onto the tip (1), and the barrier (5) is displaced downwardly, the liquid contents can exit through the side slot (8) by flowing around the barrier (5), as shown in Figure 4, which is an upside-down vertical section. The arrow (10) in Figure 4 demonstrates the fluid path flow. The stud (6) of cap (2) is designed so that the stud (6) serves as a leak-proof closure for the bottle upon recapping after activation. Other embodiments shown in Figure 4A and 4B as previously discussed.

- 6 -

Another aspect of this invention which represents a significant improvement in the manufacturing process deals with the method of creating the flow restriction. The flow restriction is created when the liquid medicament must pass through an orifice with a very small area. For injection molding this usually means an opening created by a metal core pin with small diameter frequently as small as 0.13 mm and a corresponding length of 1 mm. Steel core pins of this size and slenderness are usually considered to be fragile cores, needing frequent maintenance and replacement. By contrast, this invention uses an open slot and a dislodgeable plastic member to create the flow restriction. Molding of a small slot has considerable advantage over molding a totally enclosed orifice, in that the very small portion of the core pin which forms the slot is fully attached to a larger core pin over its entire length and is no longer fragile.

The ophthalmic dispensing tip and cap of this invention can be injection molded of a suitable plastic, such as polyethylene or polypropylene.

In one preferred embodiment, the tip of this invention is molded as part of a bottle having a limited displacement side member as illustrated in Figure 5. The combination of a limited displacement bottle and the flow restriction in the instant dispensing tip are a way to prevent streaming. Figure 5 is a diagrammatic view of this embodiment of the ophthalmic container including the tip and cap of the instant invention. As noted, the invention of the bottle of Figure 5 is an independent invention, previously filed on Dec. 22, 1993, U.S.S.N. 08/200,676.

Figure 5 shows the tip and cap of the present invention in place on the bottle of the independent invention, comprised of a compressible plastic container or vial (20), a cap member (21), and a bottom closure (22). Container or vial (20) contains a supply of liquid (23), medicament for instance, to be dispensed in droplet form. The container (20) has an integral reduced diameter open neck portion (24) provided with external helical screw threads (25) over the uppermost part of the neck end portion as shown in Figure 5. The screw threads



- 7 -

(25) are adapted to matingly engage internal threads (26) on cap member (21) to thereby attach the latter in place on container (20) in liquid-tight relation thereto.

Cap member (21) comprises a generally cylindrical  
5 mounting or base portion (27) and a inside nozzle end portion stud (28) projecting endwise therefrom.

10

15

20

25

30

- 8 -

WHAT IS CLAIMED IS:

- 5           1.     An ophthalmic tip and cap system providing nonstreaming drop control, the tip having an internally molded dislodgeable barrier which may be hinged on one side, the cap having a stud shaped to fit inside the nozzle tip, so that the downward axial movement of the cap either partially or completely displaces the barrier.
- 10           2.     The tip of Claim 1, in which the tip has molded flow restriction groove(s) or slot(s) on the internal flow channel of the tip.
- 15           3.     The cap of Claim 1 in which the tip barrier is partially displaced by the downward movement of the cap and subsequent mechanical captivation of the barrier in its open position to create a flow restriction.
- 20           4.     The cap of Claim 1 in which the tip barrier is completely displaced by the downward movement of the cap and subsequent mechanical captivation of the barrier in its open position to create a flow restriction.

25

30

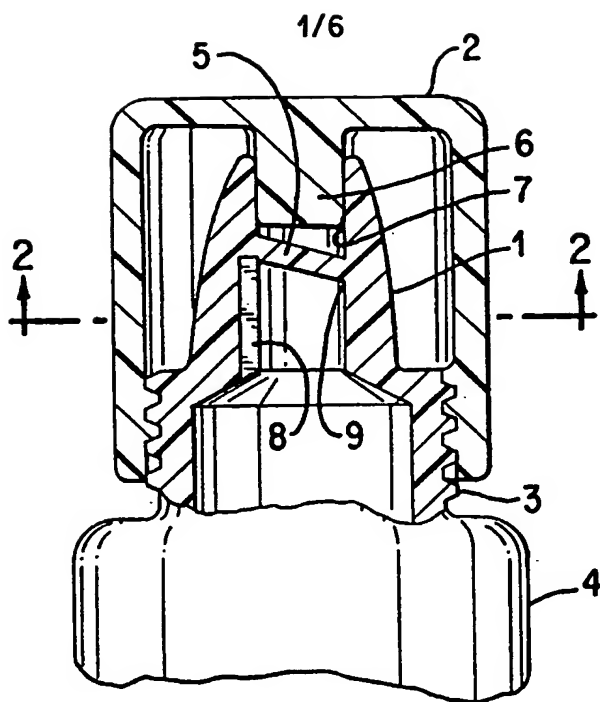


FIG. 1

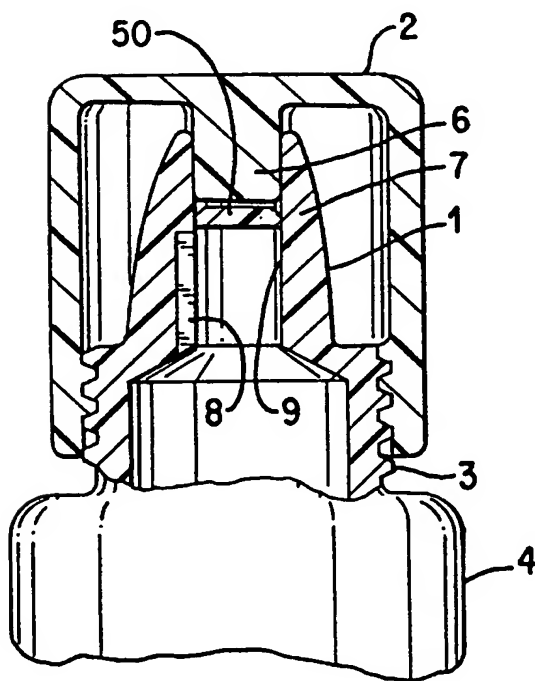


FIG. 1A  
SUBSTITUTE SHEET (RULE 26)

2/6

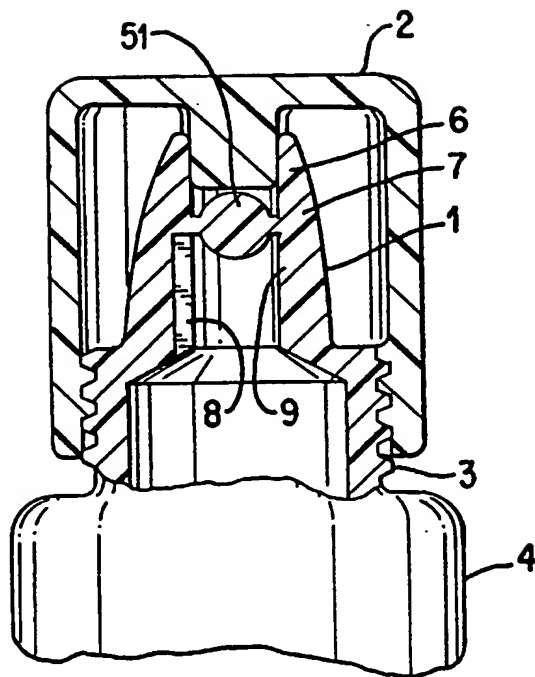


FIG. 1B

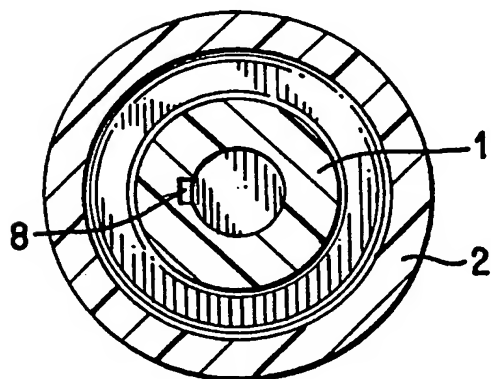


FIG. 2

3/6

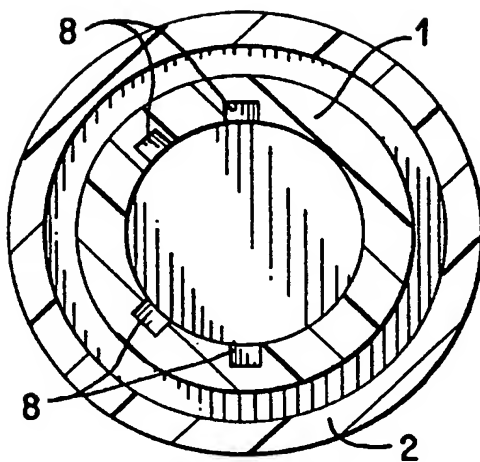


FIG. 2A

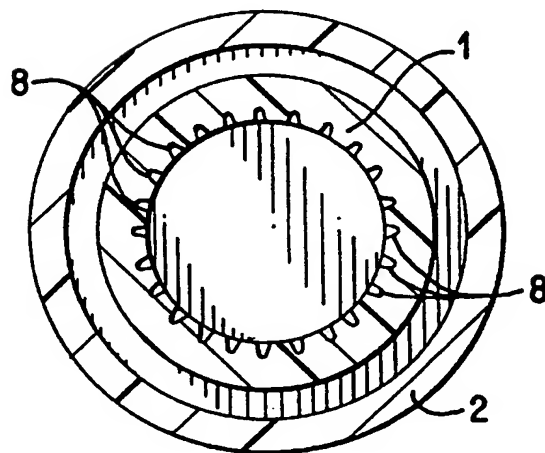


FIG. 2B

4/6

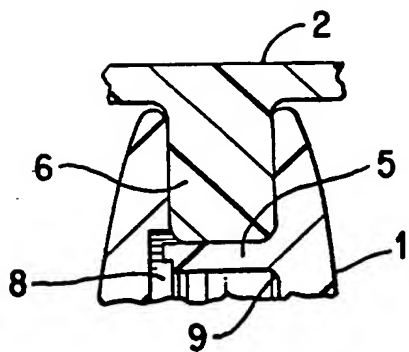


FIG. 3

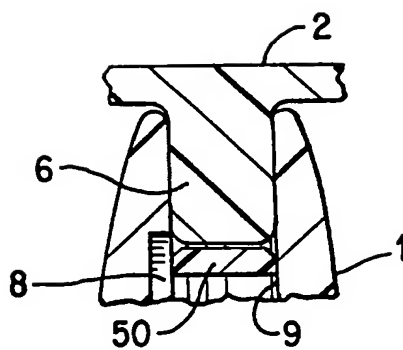


FIG. 3A

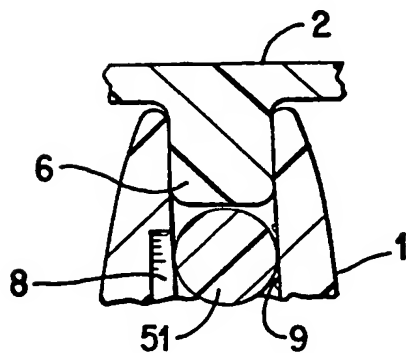


FIG. 3B

SUBSTITUTE SHEET (RULE 26)

5/6

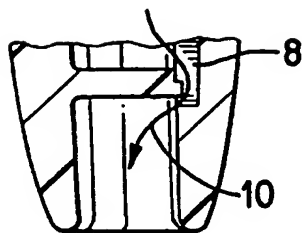


FIG. 4

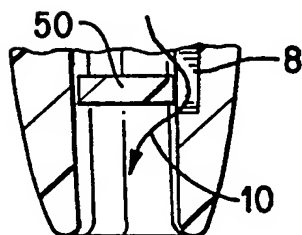


FIG. 4A

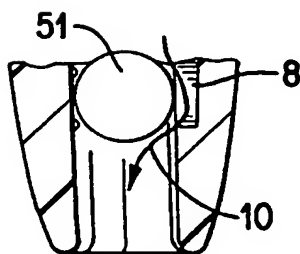
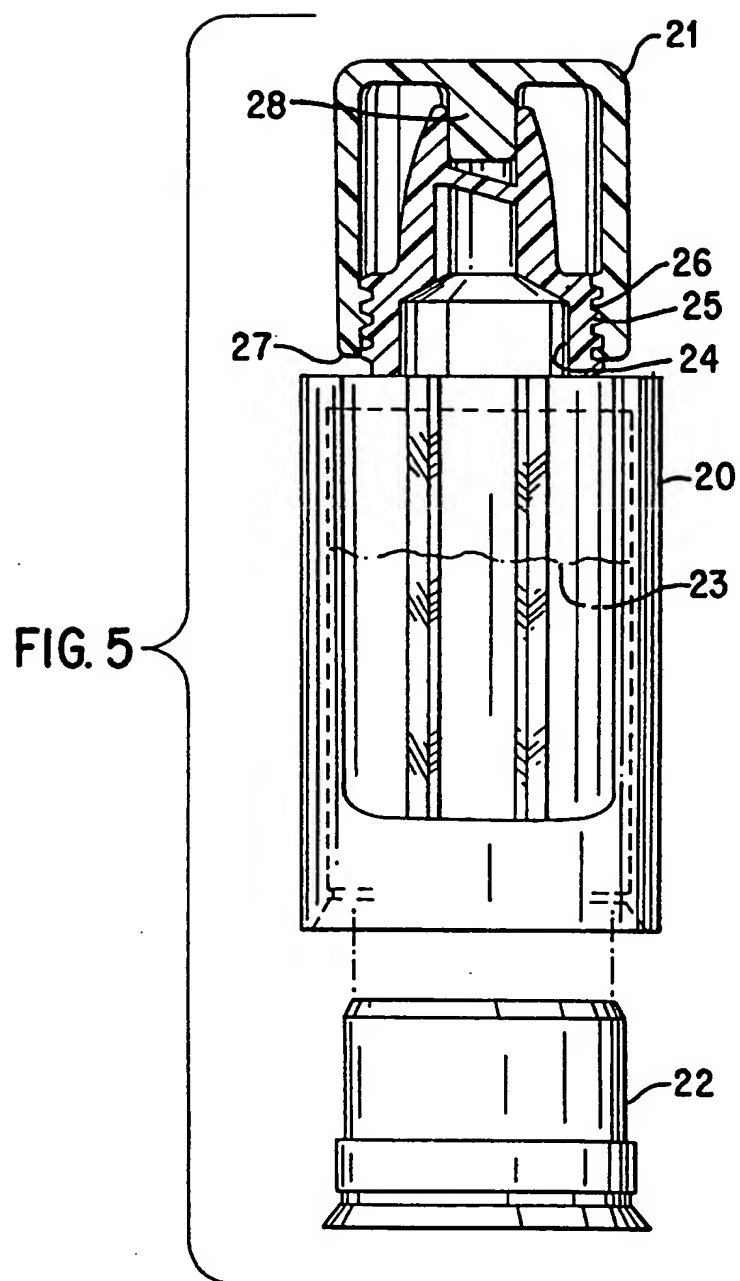


FIG. 4B

6/6





## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US95/07708

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(6) :B65D 47/18 US CL :222/83, 420; 401/132, 262 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 222/83, 83.5, 420-422, 541; 401/132, 262 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched NONE Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) NONE		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,052,589 (O'MEARA) 01 October 1991, see entire patent.	1, 3
Y	EP, A, 0 228 751 (FONTANA ET AL.) 15 July 1987, see entire patent.	1, 3
Y	IT, A, 372497 (SOCIETA ANONIMA AMUCHINA) 30 June 1939, see element c.	2
Y	US, A, 2,411,435 (S. KIRSCHENBAUM) 19 November 1946, see Figs. 15 and 17.	2
Y	US, A, 2,671,577 (F. REMINGTON ET AL.) 09 March 1954, see Fig. 10.	4
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
*A*	document defining the general state of the art which is not considered to be part of particular relevance	*T* later documents published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*E*	earlier documents published on or after the international filing date	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*L*	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*O*	document referring to an oral disclosure, use, exhibition or other means	*Z* document member of the same patent family
*P*	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 23 AUGUST 1995		Date of mailing of the international search report 26 SEP 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer <i>Stacia Simcik</i> STEVEN A. BRATLIE Telephone No. (703) 308-2669